



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: September 27, 2018

Subject: Efficacy Review for Jesse, EPA File Symbol: 6297-E
(DP Barcode: 447233, E-Submission: 29285)

From: Thao Pham
Efficacy Evaluation Team
Product Science Branch
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Thru: Kristen Willis, Team Leader
Product Science Branch
Antimicrobials Division (7510P) *Kristen Willis*
Signed: October 9, 2018

To: Eric Miederhoff, Team 31 / Karen Leavy
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Bissell Homecare, Inc.
370 Wabasha Street North
St. Paul, MN 55102

Formulation from the Label:

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈)	
dimethyl benzyl ammonium chlorides	0.21%
Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chlorides	0.21%
<u>Other Ingredients</u>	99.58%
Total	100.00%

I BACKGROUND

Product Description (as packaged, as applied): Liquid concentrate

Submission type: New Registration

Currently registered efficacy claim(s): none

Requested action(s): Add sanitizer claims against bacteria.

Documents considered in this review:

- Letter from applicant to EPA dated May 17, 2018
- Data Matrix (EPA Form 8570-35)
- 1 efficacy study (MRID 50588911)
- Certificates of Analysis (MRID 50588902)
- Proposed label dated August 3, 2018
- Confidential Statement of Formula (EPA Form 8670-4) dated 05/17/18.

II PROPOSED DIRECTIONS FOR USE

“How to use (in) (with) (CrossWave) (machine):

1. Fill machine formula tank with warm water to Water fill line as directed in the machine User Guide. Then add formula to Formula fill line. Please note large and small area cleaning tank fill lines as directed in the User Guide. Cap tank and return to machine.
2. Use machine as directed in the User Guide under the heading “**Cleaning Your Hard Floors**”. To clean, hold the spray trigger to apply solution to floor. To achieve sanitization, ensure floor is thoroughly wet and allow floor to remain wet for 5 minutes.
3. Empty (dirty water) (pick-up) tank down the drain.
4. Flush tank, filter and float with clean water after use. Allow to air dry.
5. Stay off cleaned area until completely dry.

Notice to User: This product is not to be used to sanitize carpets, rugs or other soft surfaces. It is only intended for use on hard, nonporous floors.

How to use (in) (with) (SpinWave) (machine):

1. Fill machine formula tank with warm water to Water fill line as directed in the machine User Guide. Then add formula to Formula fill line. Please note large and small area cleaning tank fill lines as directed in the User Guide. Cap tank and return to machine.
2. Use machine as directed in the machine User Guide under the heading “**Cleaning Your Sealed Hard Floors**”. Push the SPRAY button to dispense solution. To achieve sanitization, ensure floor is thoroughly wet and allow floor to remain wet for 5 minutes.
3. Stay off cleaned area until completely dry.

Note: Any solution remaining in the clean water tank should be emptied prior to machine storage.”

III STUDY SUMMARIES

1.	MRID	50588911	Study Completion Date:	01/31/18
Study Objective		Non-Food Contact Surface Sanitizer		
Testing Lab, Lab Study ID		Accuratus Lab Services, Project #A24787		
Test organism(s) <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Enterobacter aerogenes</i> (ATCC 13048) <i>Staphylococcus aureus</i> (ATCC 6538)		
Test Method		ASTM 1153-14, Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (copy provided); Protocol #BLL01110117.NFS		
Application Method		Sprayed at a distance of 6-8 inches for 3 seconds		
	Name/ID	Project Z2733 Hard Surface Sanitization Concentrate		
	Lots	BHC092-14A, BHC092-14B, BHC092-14C		

Test Substance Preparation	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3						
	Preparation	Tested concentration: LCL Dilution: 1:7 (1-part test substance + 6 parts water) Diluent: 400 ppm AOAC Synthetic Hard Water					
Soil load		5% FBS					
Carrier type, # per lot		5 glass carriers (1-inch x 1-inch) per batch contaminated with 0.02 mL culture					
Test conditions		Contact time	4 min 50 sec.	Temp	20°C	RH	10%
Neutralizer		D/E Neutralizing Broth					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		n/a					

IV STUDY RESULTS

Disinfection – Bactericidal Efficacy

MRID	Organism	Percent Reduction			Average log ₁₀ CFU/Carrier
		Batch BHC092-14A	Batch BHC092-14B	Batch BHC092-14C	
4 minute 50 second contact time, 400 ppm hard water, 5% soil load, 1:7 dilution					
50588911	Enterobacter aerogenes (ATCC 13048)	>99.9%	>99.9%	>99.9%	5.94
	Staphylococcus aureus (ATCC 6538)	>99.99%	>99.99%	>99.99%	6.21

V STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
50588911	Sanitizer, bactericidal	Hard, non-porous surfaces	Liquid, Project Z2733 Hard Surface Sanitization Concentrate	4 minutes 50 seconds	5%	400 ppm AOAC Synthetic Hard Water	<ul style="list-style-type: none"> • <i>Enterobacter aerogenes</i> (ATCC 13048) • <i>Staphylococcus aureus</i> (ATCC 6538) 	Yes

VI LABEL COMMENTS

Label Date: August 3, 2018

1. The proposed label claims that the product, Jesse, when diluted at 1 part test substance to 6 parts water, is an effective floor sanitizer against the following on hard, non-porous surfaces in the presence of 5% organic soil for a 5-minute contact time:

Enterobacter aerogenes (ATCC 13048)

Staphylococcus aureus (ATCC 6538)

These claims are **acceptable** as they are supported by the submitted data.

2. Make the following changes to the proposed label:
 - a. On page 2 of the label, remove “eliminator” where associated with bacteria. Submitted data does not demonstrate that bacteria are eliminated.
 - b. On pages 2, 6-10 and 12-13 of the label, for all “2-in-1”, “3-in-1”, “4-in-1”, “5-in-1”, “dual action” and “triple action” claims, remove parentheses around qualifiers for each claim. Each claim must be clearly qualified.
 - c. On page 3 of the label, remove the parentheses from “sealed” and “non-porous” in the recommended use table. These qualifiers are not optional.
 - d. On page 4 of the label:
 - i. Clearly separate cleaning instructions from sanitization instructions and provide clear headers for each.
 - ii. Revise the use directions to include the specific volume of product per volume of water needed to achieve the ratio supported by efficacy data.
 - iii. Instructions should specify that floors should be visibly clean for sanitization treatment. Any visible soil should be removed prior to sanitizing.
 - e. On page 6 of the label:
 - i. remove the parentheses from “99.9%” in the claim “Eliminates (99.9%) of (bacteria).” This qualifier is not optional when used in combination with eliminates.
 - ii. Revise the claim “Cleans, sanitizes, refreshed pet messes”. Messes can be cleaned but not sanitized.
 - iii. Remove claims for “staph”. Efficacy testing data was submitted for *Staphylococcus aureus* only. This claim implies efficacy against the entire genus which was not demonstrated.
 - f. On pages 6-7 of the label:
 - i. Remove all “fast”, “easy”, and “quick” claims. Claims for fast or quick are limited to contact times of 30 seconds or less.
 - ii. Clarify all “one step”, “sanitizes as it cleans”, and “cleans as it sanitizes” claims with “when used according to sanitization instructions.”

- g. On pages 6-8 and 13 of the label, remove all “all-in-one” claims. An acceptable alternative is “multipurpose”.
- h. On page 7 of the label:
 - i. Qualify “(X) in 1” with values for x and clearly define claims for X.
 - ii. Remove “improves cleaning performance to also sanitize” as this claim may be confusing for the user. Cleaning and sanitizing have separate use directions with different contact times; therefore, label claims should clearly distinguish between these two claims.
 - iii. Remove or qualify “(Eliminates) bacteria” as this claim implies total kill.
- i. On pages 7-9 of the label, remove claims which imply enhanced efficacy, such as “beyond surface cleaning”, “powerful”, “higher level”, “best”, “clean beyond what’s seen”, “toughest soils”, and “dramatically enhances the cleaning performance”.
- j. On pages 8-11 of the label, remove all “greater than”, “more than”, “over” 99.9% claims. This language is too broad and may imply enhanced efficacy.
- k. On page 9 of the label:
 - i. Remove “fast”.
 - ii. Define “x” in “(x%) (of) (non-living) allergens”.
- l. On page 10 of the label:
 - i. Remove “unbeatable cleaning” as this implies enhanced efficacy.
 - ii. Remove unqualified “eliminates” claim, which implies complete kill when associated with bacteria.
 - iii. Remove claims which imply residual product activity such as “permanently”, “controls the growth”, “controlling the growth of mold and mildew”.
- m. On page 11 of the label, remove “prevents” as this claim implies residual activity.
- n. On pages 11-13 of the label, remove “advanced” as this implies enhanced efficacy.
- o. On page 12 of the label, qualify “use throughout your house” with “hard, nonporous, nonfood contact surfaces”.
- p. On page 13 of the label, remove “Complete Clean”.